

UNITED STATES PATENT AND TRADEMARK OFFICE


In re application : Walter Schubert  
 Application No. : 10/664,678  
 Filed : September 12, 2003  
 Confirmation No. : 4058  
 For : USE OF SUBSTANCES WITH IMMUNOMODULATING  
 ACTIVITY FOR THE TREATMENT OF AMYOTROPHIC  
 LATERAL SCLEROSIS

Examiner :  
 Attorney's Docket : S&H-010DX

TC Art Unit: 1614

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 12-10-03.

By:   
 Charles L. Gagnebin III  
 Registration No. 25,467  
 Attorney for Applicant(s)

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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

Sir:

It is desired to cite for the record in this application the enclosed references listed on the attached copy of PTO Form #1449. The paragraph(s) marked below are applicable to this Information Disclosure Statement.

- [X] (1) Pursuant to 37 C.F.R. § 1.97(b)(1) and (2), the attached Information Disclosure Statement is being filed within three months of the filing date of the above identified national application or within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 of the above identified application. Accordingly, applicant(s) believes that no fee or statement under 37 C.F.R. § 1.97(e) is required.

- ☐ (2) Pursuant to 37 C.F.R. § 1.97(b)(3), applicant(s) believes the attached Information Disclosure Statement is being filed before the mailing date of a first Office action on the merits. Accordingly, applicant(s) believes that no fee or statement under 37 C.F.R. § 1.97(e) is required.
- ☒ (3) Pursuant to 37 C.F.R. § 1.97(b)(4), applicant(s) believes the attached Information Disclosure Statement is being filed before the mailing date of a first Office action after the filing of a request for continued examination under § 1.114. Accordingly, applicant(s) believes that no fee or statement under 37 C.F.R. § 1.97(e) is required.
- ☐ (4) Pursuant to 37 C.F.R. § 1.97(c), the attached Information Disclosure Statement is being filed before the mailing date of a final action or a notice of allowance and is accompanied by:
- ☐ a statement under 37 CFR § 1.97(e); or
- ☐ the fee set forth in § 1.17(p).

PETITION UNDER 37 CFR § 1.97(d)

- ☐ (5) Pursuant to 37 CFR § 1.97(d), applicant(s) hereby petitions the Commissioner to consider the attached Information Disclosure Statement which is being filed on or before payment of the issue fee. This petition is accompanied by a statement under 37 C.F.R. § 1.97(e) and the petition fee set forth in 37 C.F.R. § 1.17(p).

STATEMENT UNDER 37 C.F.R. § 1.97(e)(1)

- ☐ (6) The undersigned hereby states that each item of information contained in the attached Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

STATEMENT UNDER 37 C.F.R. § 1.97(e)(2)

- ☐ (7) The undersigned hereby states that no item of information contained in the attached Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, no item of

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information contained in the attached Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

The filing of this Information Disclosure Statement is not a representation by the undersigned as to personal knowledge of the contents of every word or phrase of the material enclosed or that reliance on other suitably trained professionals has not been made.

If a search report of a searching agency is enclosed identifying the nature of the relevance of each document, such a designation is deemed to satisfy 37 C.F.R. § 1.98(a)(3) even if in a foreign language because the codes are the same in all languages. However, applicant(s) does not necessarily adopt the position reflected by that report.

These references were cited in related Patent Nos. 6,638,506 and 6,638,515, issued respectively on October 28, 2003 and related Application Nos. 09/802,305 and 09/803,614 filed respectively on March 8, 2001.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 23-0804. Triplicate copies of this letter are enclosed.

Respectfully submitted,

WALTER SCHUBERT

By: 

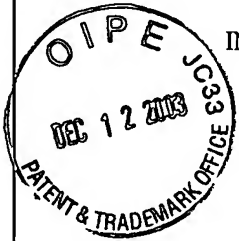
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CLG/mes/299184  
Enclosure

Date: December 10, 2003

Page 1 of 2

Form PTO-1449  
(REV. 8-83)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.  
S&H-010DXAPPLICATION NO.  
10/664,678INFORMATION DISCLOSURE CITATION  
(Use several sheets if necessary)

APPLICANT: Walter Schubert

FILING DATE  
9/12/03

GROUP

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE*

## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
DE 197 23 690 A**	3/26/98	Germany (English Abstract)			

## OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

	"Fundamental Immunology", Paul W.E. ed. Lippincott-Raven Publishers, Philadelphia, 1999, pp. 66-67 of Chapter 3**
	Pullen et al., "Ultrastructural analysis of spinal motoneurons from mice treated with IgG from ALS patients, healthy individuals, or disease controls", J. Neurol. Sci. 20-00; 180:35-45**
	Obal et al., "Recruitment of activated microglia cells in the spinal cord of mice by ALS IgG", NeuroReport 2001; 12:2449-2452**
	Schubert, et al., "Detection by 4-parameter microscopic imaging and increase of rare mononuclear blood leukocyte types expressing..." Neuroscience Letters, vol. 198, no. 1, 9/22/95**
	Kahan, "immunosuppressive therapy" Cur. Opin. Immunol. 4:553-560 1992**
	Tan et al., "Immunosuppressive Treatment of Motor Neuron Syndromes", Arch Neurol. 51:194-200 1994**
	Dalakas et al., "Effect of High-Dose Intravenous Immunoglobulin on Amyotrophic Lateral Sclerosis and Multifocal Motor Neuropathy", Arch Neurol. 51:861-864 1994**
	Ludolph J., "Treatment of amyotrophic lateral sclerosis - What is the next step?", Neurol. 247:13-18 2000**
	Serratrice et al., "Overview of the Pathogenesis and Therapy of Amyotrophic Lateral Sclerosis", Adv. Neurol 68:1-5 1995**
	D.D.F. Ma et al., "Synthetic oligonucleotides as therapeutics" the coming of age", Biotechnology Annual Review, Vol. 5, pp. 155-196**
	C. Frank Bennett et al., "Pharmacology of Antisense Therapeutic Agents", Methods in Molecular Medicine: Antisense Therapeutics, pp. 13-46**
	Andrea D. Branch, "A good antisense molecule is hard to find", TIBS 23 - February 1998, pp. 45-50**
	W. Michael Flanagan et al., "Cellular penetration and antisense activity by a phenoxazine-substituted heptanucleotide", Research, pp. 1-5**
	Hans Fritz et al., "Cationic Polystyrene Nanoparticles: Preparation and Characterization of a Model Drug Carrier System for Antisense Oligonucleotides", Journal of Colloid and Interface Science, 195, pp. 272-288**

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*\*THESE REFERENCES CAN BE FOUND IN RELATED PATENT NOS. 6,638,506, AND 6,638,515 AND APPLICATION NOS. 09/802,305 AND 09/803,614

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Page 2 of 2

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## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

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	Kuang-Yu Jen et al., Stem Cells, 2000; 18; pp. 307-319
	Sudhir Agrawal, Antisense Oligonucleotides: towards clinical trials, TIBTECH, October 1996; Vol. 14, pp. 376-387
	Douglas W. Green, et al., Antisense Oligonucleotides: An Evolving Technology for Modulation of Gene Expression in Human Disease, COLLECTIVE REVIEW, Journal AM. Coll. Surg.; pp. 93-105
	Traian V. Chirila et al., "The use of synthetic polymers for delivery of therapeutic antisense oligodeoxynucleotides", Biomaterials 23 (1992) pp. 321-342
	Sudhir Agrawal et al., "Antisense therapeutics: is it as simple as complementary base recognition?", Molecular Medicine Today; February 2000, Vol. 6, pp. 72-81

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